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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,615	12/30/2003	Arnold P. Nerenberg	NERE-3815	7492

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EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/748,615	<b>Applicant(s)</b> NERENBERG, ARNOLD P.	
	<b>Examiner</b> Traviss C. McIntosh	<b>Art Unit</b> 1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/30/03</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation. Applicants are not enabled for the combinations as instantly claimed.

Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below as seen in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). A conclusion of lack of enablement means that, based on the evidence regarding a fair evaluation of an appropriate combination of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

These factors include:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and

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- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

**The breadth of the claims - The nature of the invention**

Claim 1 is drawn to a nutritional supplement comprising L-arginine-2-pyrrolidone-5-carboxylate, L-lysine hydrochloride, and a cortisol suppressant. Claims 2-4 limit the cortisol suppressant. Claims 5-14 add additional agents to the composition, such as L-leucine (claim 5), bee pollen (claim 6), L-tyrosine (claim 7), etc. Claim 15 provides the composition does not include a steroid or hormone. Claims 16-20 provide the form of the supplement, i.e. powder, tablets, wafers, liquid, or capsule form. Claim 21 is drawn to a nutritional supplement consisting essentially of L-arginine-2-pyrrolidone-5-carboxylate, L-lysine hydrochloride, and a cortisol suppressant. Claims 22-26 limit the composition and the cortisol suppressant. Claims 27-31 limit the form of the supplement. Claim 32 is drawn to a nutritional supplement consisting essentially of L-arginine-2-pyrrolidone-5-carboxylate, L-lysine hydrochloride, a cortisol suppressant, and an additional agent. Claims 31-52 limit the additional agent. Claims 53-57 limit the form of the supplement.

**The state of the prior art**

L-arginine-2-pyrrolidone-5-carboxylate and L-lysine hydrochloride are known to provide a synergistic effect in increasing the release of pituitary somatotrophin (HGH) and insulin, as seen by Isidori et al. (see applicants IDS). Acetyl-L-carnitine is known to be capable of restoring the integrity of the cardiac mitochondrial membrane altered by aging, thereby restoring the normal activity of cytochrome oxidase which allows for a more efficient oxidative phosphorylation and therefore improves cardiac performance in aged animals, as seen by US

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5,977,162. Maltodextrin is known in the art to be a sweetener. Combination therapy, and drug-drug interactions are known in the art to have various effects, and when physicians use several drugs in combination, they face the problem of knowing whether a specific combination in a given patient has the potential to result in an interaction, and if so, how to take advantage of the interaction if it leads to improvement in therapy or how to avoid the consequences on an interaction if they are adverse. A potential drug interaction refers to the possibility that one drug may alter the intensity of the pharmacological effects of another drug if given concurrently. The net result may be enhanced or diminished effects of one or both of the drugs, or the appearance of new effects which is not seen with either drug alone. The frequency of significant beneficial or adverse effects is unknown. The interaction between the drugs may be pharmacokinetic, i.e. alteration of the absorption, distribution, or elimination of one drug by another, or may be pharmacodynamic, i.e. interactions between agonists and antagonists at drug receptors. The most important drug-drug interactions occur with drugs that have serious toxicity and low therapeutic index, such that relatively small changes in drug level can have significant adverse consequences. Additionally, drug-drug interactions can be clinically important if the disease being controlled with the drug is serious or potentially fatal if left under treated. Drugs are known to interact at any point during their absorption, distribution, metabolism, or excretion; the result being an increase or decrease in concentration of the drug at the site of action. As individuals vary in their rates of disposition of an given drug, the magnitude of an interaction that alters pharmacokinetic parameters is not always predictable, but can be very significant. See Goodman & Gilman's: The Pharmacological Basis of Therapeutics, 10<sup>th</sup> Edition, McGraw-Hill Medical Publishing Division, 2001, pages 54-56.

**The level of predictability in the art**

As seen by Goodman & Gilman, the art of combination therapy is unpredictable. Drug-drug interactions are known to be beneficial or adverse, yet there is no way to know until the drugs are actually tested in combination with each other. Especially in view of the fact that Isidori et al. show that the combination of L-arginine-2-pyrrolidone-5-carboxylate and L-lysine hydrochloride increase plasma HGH levels from about 10-15 ng/ml when using either of the drugs individually to about 90 ng/ml when using a combination, after 90 minutes. This highly synergistic effect shows that the combination of two agents produced unexpected results.

**The amount of direction provided by the inventor**

The instant specification is not seen to provide adequate guidance which would allow the skilled artisan to extrapolate from the disclosure and examples provided to use the claimed method commensurate in the scope with the instant claims. There is a lack of data and examples which adequately represent the claims as written. Applicants have not provided any indication of what drugs might be toxic and what the drugs therapeutic indexes are. Applicants have merely listed various drugs in the specification.

**The existence of working examples**

There are no working examples in the instant application. There are no formulations made, and nothing tested in any capacity on any subjects. Applicants state that “each ingredient of the nutritional supplement of the present invention may be prepared in accordance with any method known to one of ordinary skill in the art. Alternatively, each ingredient may be obtained in a fully prepared from a commercially available source” (see page 10 of specification).

Applicants also state that “the dissolvable form may be prepared by any method known to one of

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ordinary skill in the art”, and that “the liquid form may be prepared by any method known to one of ordinary skill in the art”. Applicants have not

**The quantity of experimentation needed to make and use the invention based on the content of the disclosure**

Indeed, in view of the information set forth supra, the instant disclosure is not seen to be sufficient to enable one to make or use the combination of the claimed agents without undue experimentation. It is noted that the specification should teach how to make and use the invention, not teach how to figure out for oneself how to make and use the invention. See *In re Gardner*, 166 USPQ 138 (CCPA 1970).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding independent claims 1, 21, and 32, the phrase "including" renders the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Applicants claim a supplement comprising a cortisol suppressant “including at least one of acetyl-L-carnitine...and maltodextrins”. It is unclear if applicants are claiming a cortisol suppressant which additionally includes the listed agents, or if applicants are claiming a composition comprising at least one cortisol suppressant

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selected from the group consisting of acetyl-L-carnitine and maltodextrins. It is believed that applicants are claiming a composition comprising at least one cortisol suppressant selected from the group consisting of acetyl-L-carnitine and maltodextrins. Removing the phrase “including” and using proper Markush language will obviate the instant rejection. It is noted that dependent claims 2-4, 24-26, and 33-42 are indefinite for containing the phrase “including” for the same reasons. The metes and bounds of the claims cannot be determined using the instant language.

All claims which depend from an indefinite claim are also indefinite. *Ex parte Cordova, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).*

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss McIntosh  
May 12, 2006

Shaojia A. Jiang  
Supervisory Patent Examiner  
Art Unit 1623

 5/15/06